

TIME	CARDIOVASCULAR						PAIN						DETAILED NEUROLOGIC ASSESSMENT															
	Cap Refill	R/L	R/L	R/L	Skin	EDEMA		Location	Pain Scale	Score	Intervention	Outcome *	Sedation Score	R/L	R/L	Traces & Fields	Blink	Ant Fontanel	MOTOR STR				Verbal Response	Eye Opening	Best Motor Response	Coma Scale Total	Consciousness	Numbness/Tingling
		Pulse UE	Pulse LEDP	Pulse LEPT		Location	Severity							Pupil Reactions	Pupil Size				R		L							
																			Upper	Lower	Upper	Lower						
08	L3	33	33	33	W. Pt	A	2+	A	F	3	M	*	2	55	33	✓	✓	-	1	1	1	1	5	3	6	14	AR	-
1000	L3	33	33	33	WA	A	2+	F	3	15	*								1	1	1	1	5	3	6	14	AR	-
0600	L3	33		33	WD	A	2+	A	F	11	M	*		?	?	?	?		1	1	1	1	4	3	5	12	AR	
0800												*																
04												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
												*																
									</																			

3-10 YEARS: FACES RATING SCALE

0 No Hurt 1 Hurts Little Bit 2 Hurts Little More 3 Hurts Even More 4 Hurts Whole Lot 5 Hurts Worst

10-18 YEARS: NUMERIC SCALE 0-5

No Pain 0 1 2 3 4 5 Worst Pain

LOCATION

A generalized D
B focal E
C F

INTERVENTION

E - Epidural (*See MAR) P - PCA (*See MAR)
M - MAR (Oral, IM, IV, SQ- See MAR) *N - Nonpharmacologic Techniques
*Evaluation - must be documented in Interdisciplinary Progress Notes.

OUTCOME

*See Notes for Duration and Evaluation

SEDATION SCORES

1 - Wide Awake
2 - Drowsy (arouses to verbal/tactile stimuli)
3 - Dozing intermittently (arouses to vigorous stimuli)
4 - Awakens when aroused (responsive to painful stimuli)
5 - Unable to arouse (notify physician)

NEUROLOGICAL

PUPIL REACTION

B - Brisk N - Non-Reactive
S - Sluggish Ø - Not Observed

PUPIL SIZE (mm)

1 3 5 7

ANT FONTANEL

S - Soft F - Full
T - Tense FL - Flat
D - Depressed

MOTOR STRENGTH

2 - Normal T - Tremors
1 - Weak S - Spontaneous
0 - None

BEST VERBAL RESPONSE

> 5 YEARS

5 - Oriented and converses
4 - Disoriented and converses
3 - Inappropriate words
2 - Incomprehensible sounds
1 - No response

EYE OPENING

4 - Spontaneous 2 - To pain
3 - To speech 1 - No response

BEST MOTOR RESPONSE

6 - < 1 yr. spontaneous; > 1 obeys
5 - Localizes Pain
4 - Flexion-withdrawal
3 - Flexion-abnormal (decorticate rigidity)
2 - Extension (decerebrate rigidity)
1 - No response

2-5 YEARS

5 - Appropriate words and phrases
4 - Inappropriate words
3 - Persistent cries and/or screams
2 - Grunts
1 - No response

0-23 MONTHS

5 - Smiles, coos appropriately
4 - Cries, consolable
3 - Persistent inappropriate crying and/or screaming
2 - Grunts / agitated / restless
1 - No response

GLASCOW COMA SCORE

*The scale scores responses from 3-15, with the lower numbers indicating a higher degree of neurologic deficit.

CONSCIOUSNESS

PA - Post Anesthesia
CS - Conscious Sedation
P - Paralyzing Agent
A - Analgesia S - Sedation
AL - Alert AR - Arousable
NR - No Response

NUMBNESS/TINGLING

PATIENT IDENTIFIER
Medical City Dallas Hospital
WILLIAMS, LABREA
H00707472988 MR#: H000826583 6/2/2002
DOB: 07/20/94 T/F Sandell, Sharon R., M.D.

-10108

[illegible]

IV SITE ASSESSMENTS

- ✓ - All IV sites are patent without discoloration, irritation, edema or tenderness
- B - Blood return verified
- * - Further documentation required (See Interdisciplinary Notes)

ENTERAL

METHOD	FORMULA	PLACEMENT CHECK
A - Assisted Feed	F - Formula	V - Verified
N - Nipple	B - Breast Milk	DURATION
B - Breast	1. _____	Number of minutes
G - Gastrostomy	2. _____	TOLERATION
Ng - Naso-gastric		P - Poor
Og - Oral-gastric		F - Fair
S - Self Feed		G - Good

Medical City Dallas Hospital

WILLIAMS, LABREA

WILLIAMS, LABREA
H00707472988 MR#: H000826583 6/2/2002

H00707472988 MR#: H000826565 3/2/95
DOB: 07/20/94 7/F Sandell, Sharon R., M.D.

Rev. 2/01) Page 5 of 10

TIME	TOTAL OUT	OUTPUT										TUBES/DRAINS											
		URINE				ULTRA-FILTRATION		GAS		STOOL		BLOOD		TUBES/DRAINS		TUBES/DRAINS		TUBES/DRAINS		TUBES/DRAINS			
		Vol	Ph	Gluc	Blood	Quantity	TOTAL	Quantity	Consistency	Hemoccult	R/S	Vol	Cum	Vol	Cum	Vol	Cum	Vol	Cum	Vol	Cum	Vol	Cum
0700	150	1.0																					
0800																							
0900																							
1000																							
1100																							
1200																							
1300	800	1.05																					
1400																							
1500	150	1.05																					
1600																							
1700																							
1800																							
1900	50	1.05																					
2000																							
2100																							
2200																							
2300																							
2400																							
0100																							
0200																							
0300	100	1.05																					
0400																							
0500																							
0600	50	1.05																					
24 hr TOTAL																							

Today's Weight: _____

Yesterday's Weight: _____

Admit Weight: _____

Birth Weight: _____

FOC: _____

PREVIOUS 24°

I: _____

O: _____

Balance: _____

Blood Out Total: _____

NUTRITION/METABOLIC PATTERN

BREAKFAST

Diet clear

☐ NPO for _____

Food Taken Per: ☐ Self ☐ Assist ☐ Fed

☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☒ None ☐ Refused

Tolerated diet w/o difficulty: ☐ Yes ☒ No

Swallow w/o difficult: ☐ Yes ☒ No

Calorie Count: ☐ Yes ☒ No

Snack: ☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None

Supplement ☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None

LUNCH

Diet clear liq.

☐ NPO for _____

Food Taken Per: ☐ Self ☐ Assist ☐ Fed

☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None ☐ Refused

Tolerated diet w/o difficulty: ☐ Yes ☐ No

Swallow w/o difficult: ☐ Yes ☐ No

Calorie Count: ☐ Yes ☐ No

Snack: ☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None

Supplement ☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None

DINNER

Diet _____

☐ NPO for _____

Food Taken Per: ☐ Self ☐ Assist ☐ Fed

☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None ☐ Refused

Tolerated diet w/o difficulty: ☐ Yes ☐ No

Swallow w/o difficult: ☐ Yes ☐ No

Calorie Count: ☐ Yes ☐ No

Snack: ☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None

Supplement ☐ All ☐ 3/4 ☐ 1/2 ☐ 1/4 ☐ None

TYPE:

M - Meconium B - Brown F - Formed S - Seedy

Y - Yellow T - Transitional L - Loose C - Constipated

G - Green W - Watery

QUANTITY:

S - Small M - Moderate L - Large C - Copious

INTAKE 8 16 24

OUTPUT 8 16 24

I & O BALANCE 8 16 24

PATIENT IDENTIFICATION

Medical City Dallas Hospital

WILLIAMS, LABREA

H00707472988 MR#: H000826583 6/2/2002

DOB: 07/20/94 7/F Sandell, Sharon R., M.D.

[illegible]

CLINICAL SERVICES DAILY COLLABORATION:			RE-PRIORITIZED PROBLEM / NEEDS / GOALS:
<input checked="" type="checkbox"/> NUR	= Nursing		Date: <u>6/3/02</u> Time: <u>0900</u>
<input type="checkbox"/> RT	= Respiratory Care		1. <u>Pain #2</u>
<input type="checkbox"/> SW/CM	= Social Worker / Case Manager		2. <u>Fever #1</u>
<input type="checkbox"/> PT	= Physical Therapy		3. <u>K/D #3</u>
<input type="checkbox"/> OT	= Occupational Therapy		4. <u>P/S #4</u>
<input type="checkbox"/> ST	= Speech Therapy		5. <u>D/C #5</u>
<input type="checkbox"/> MNT	= Medical Nutrition Therapy		6. _____
<input type="checkbox"/> CNS	= Clinical Nurse Specialist		7. _____
<input type="checkbox"/> CLS	= Child Life Specialist		8. _____
<input type="checkbox"/> Other:			9. _____
			10. _____
			Signature / Title: <u>mkjingen</u>
DATE & TIME	DISCIPLINE	ACTION	SIGNIFICANT FINDINGS
6/3/02 0905	NUR	D	Report received. Assessment complete & complete precautions. Afebrile at this time. C/o pain from itching so much. Tylenol & Benadryl administered per orders. BBS CTA. O2sat 100%. RA. Entire body covered in red lesions & pustules. Upper half body more severe than lower half. Instructed on trying not to itch lesions. Urine Dipstick obtained SG 1.010, Blood moderate. Team leader notified. IV infusing LR @ 150cc/hr. Will monitor closely. Arzeneo bath to be done by mom in the next 30 min. Will keep informed. <u>mkjingen</u>
0920	NUR	D	T 38.5 ax. Tylenol administered @ 0910. Will monitor. <u>mkjingen</u>
0945	NUR	D	IV rate ↓ to 100cc/hr due to occlusion status. Will monitor. <u>mkjingen</u>
1030	NUR	E	T 37.5 ax. <u>mkjingen</u>
1100	NUR	D	Pt C/o pain @ IV site p getting it wet. Repositioned tape, but no ora-

ACTION CODES: D = Data I = Intervention E = Evaluation

PATIENT IDENTIFICATION

Medical City Dallas Hospital
 WILLIAMS, LABREA
 H00707472988 MR#: H000826583 6/2/2002
 DOB: 07/20/94 7/F Sandell, Sharon R., M.D.

-11312

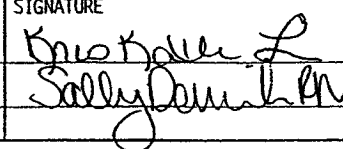
DATE & TIME	DISCIPLINE	ACTION	SIGNIFICANT FINDINGS
		cont -	relief obtained. Signs of infiltration begun. IV was removed. mprng
6/3/02 1145	nur	D	IV restarted under sterile technique w a 22 gauge needle. flushing's complication. Pt. tolerated very well. will re-start fluids and monitor. mprng
6/3/02 1200	NUR	D	Assessment completed - see flow sheet. Pt. awake & c/o itching. Pt. calling out for grandmother & sibling. Informed pt. that only pt's mother was at bedside. Pt.'s entire upper body (from waist up) covered in lesions. Pt's eye closed, but open to verbal stimuli. Pt. up to bathroom w assistance voided 200cc spec gravity 1.005. HR 130s, cardiac & pulse ox monitors intact. POC discussed w mother. Armboard applied. MS Jellen
6/3/02 1320	NUR	DI	Pt. c/o chills, covered under 2 blankets. Tylenol & Benadryl administered per M.D. order. Educated pt. on importance of to itching scratching. MS Jellen
6/3/02 1715	NUR	DI	Temp 39.4° axillary. Attempted Ibuprofen p.o.; however, pt. refused any p.o. Ibuprofen given rectally. Dr. Matson in to see pt. HR 130-140s. MS Jellen
6/3/02 1800	NUR	E	Pt. continuing to talk & call out for people she knows but are not present in her room.

PATIENT IDENTIFICATION

Continued

Medical City Dallas Hospital
WILLIAMS, LABREA
 H00707472988 MR#: H000826583 6/2/2002
 DOB: 07/20/94 705 Sendell, Sharon R., M.D.

Date: 06/02/02 Time: 0025		MEDICATION ADMINISTRATION RECORD Medical City Dallas Hospital				Page 2	
WILLIAMS, LABREA H00707472988 H.60 H.601D-1 Sandell, Sharon R., M.D.		DIAGNOSIS: RASH FEVER WEIGHT: 39.000kg HEIGHT: 0.4" (1.0) BSA: 0.17 UNIT #: H000826583 ADMIT DATE: 06/02/02 AGE/SEX: 7/F ALLERGIES: NO KNOWN DRUG ALLERGIES NOTES:					
CHECKED BY: _____							
ADMINISTRATION PERIOD: 06/02/02 (0715) - 06/03/02 (0714)		START/STOP: 0715-1514		1515-2314		2315-0714	
***** PRN MEDS * *****							
IBUPROFEN TAB(MOTRIN/ADVIL) DOSE: 400 MG ROUTE: ORAL FREQ: PRN Q 6 hours COMMENTS: PRN T > = 101 UNRESPONSIVE TO TYLENOL USE FOR ADVIL/MOTRIN *** PYXIS ITEM ***		RX #: 06409222 06/02/02 07/02/02		2030 8D		0400 SD	
ACETAMINOPHEN BTL(TYLENOL DROPS) DOSE: 580MG=5.8ML ROUTE: ORAL FREQ: PRN Q 4 hours COMMENTS: PRN TEMP > 102 OR PAIN USE FOR TYLENOL DROPS (NOT TO EXCEED 65MG/KG/DAY) *** PYXIS ITEM ***		RX #: 06409958 06/02/02 07/02/02		2345 SD		0030	
DIPHENHYDRAMINE HCL CAP(BENADRYL CAP) DOSE: 25 MG ROUTE: ORAL FREQ: PRN Q 6 hours COMMENTS: PRN ITCHING (USE FOR BENADRYL) *** PYXIS ITEM ***		RX #: 06409960 06/02/02 07/02/02		0000 K		2030 SD	
Benadryl 25mg IV Q 6° prn itching		1°		1500 K			
Diprune for specific gravity Q 6°				1330 K 1530 K		1930 K 0200 voided in bed	
Benadryl 25mg IV Q 4°						0035 SD 0400 SD	

MEDS NOT GIVEN	INJECTION SITES	SIGNATURE	INITIALS	SIGNATURE	INITIALS
1-NPO	R-RIGHT AB-ABDOMEN				
2-REFSED	L-LEFT U-UPPER				
3-N/V	D-DELTOID M-MID				
4-DRS ORDRS	G-GLUTEAL				
5-OTHER	T-THIGH				

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H.601D-1

Page: 2

-23115

Date: 06/02/02 Time: 0025	MEDICATION ADMINISTRATION RECORD Medical City Dallas Hospital	Page: 3
WILLIAMS, LABREA H00707472988 H.60 H.601D-1 Sandell, Sharon R., M.D. CHECKED BY: _____	DIAGNOSIS: RASH FEVER WEIGHT: 39.000kg HEIGHT: 5' 0.4" (1.0) BSA: 0.17 UNIT #: H000826583 ADMIT DATE: 06/02/02 AGE/SEX: 7/F ALLERGIES: NO KNOWN DRUG ALLERGIES NOTES:	
ADMINISTRATION PERIOD: 06/02/02 (0715) - 06/03/02 (0714) START/STOP 0715-1514 1515-2314 2315-0714		
DEXTROSE 5% 1/2 NS 1000 ML POTASSIUM ACETATE 20 MEQ WILLIAMS, LABREA H00707472988		0400 SD

MEDS NOT GIVEN	INJECTION SITES	SIGNATURE	INITIALS	SIGNATURE	INITIALS
1-NPO	R-RIGHT AB-ABDOMEN			<i>Sally Demetriou</i> SD	SD
2-REFSED	L-LEFT U-UPPER				
3-N/V	D-DELTOID M-MID				
4-DRS ORDRS	G-GLUTEAL				
5-OTHER	T-THIGH				

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H.601D-1

Page: 3

-24-116

Date: 06/03/02 Time: 0000		MEDICATION ADMINISTRATION RECORD Medical City Dallas Hospital		Page 1	
WILLIAMS, LABREA H00707472988 H.60 H.601D-1 Sandell, Sharon R. M.D. CHECKED BY: <i>Sally Demich</i>		DIAGNOSIS: RASH FEVER WEIGHT: 39.000kg. HEIGHT: 5' 0.4" (1 0) BSA: 0 17 UNIT # H000826583 ADMIT DATE: 06/02/02 AGE/SEX: 7/F ALLERGIES: NO KNOWN DRUG ALLERGIES NOTES:			
ADMINISTRATION PERIOD: 06/03/02 (0715) - 06/04/02 (0714)		START/STOP		0715-1514 1515-2314 2315-0714	
***** SCHEDULED MEDS * *****					
NACL 0.9% 32.5 ML CLINDAMYCIN PHOSPHATE (CLEOCIN PHOSPHATE) 390 MG RATE: 65 MLS/HR IV COMMENTS: 12MG/ML (MAX 12MG/ML) VIAL 150MG/ML (NO DILUTION) USE FOR CLEOCIN USE IF PT > 2 YEARS OF AGE		RX #: 06409224	06/02/02 1200 <i>mt</i>	1800 <i>mt</i> 1930 <i>SD</i>	0000 <i>SD</i> 0600 <i>SD</i>
NACL 0.9% 20 ML RANITIDINE (ZANTAC VIAL) 50 MG RATE: 40 MLS/HR IV COMMENTS: 2.5MG/ML (MAX) 1/P// ZANTAC 2.5MG/ML ALIQUOT		RX #: 06409955	06/02/02 1300 <i>mt</i>	2100 <i>SD</i>	0500 <i>SD</i>
acyclovir 780 mg Q6° IV x 20 doses			1100 <i>mt</i>	1800 <i>mt</i>	0000 <i>SD</i> 0600 <i>SD</i>
Dipstick Urine Q6° for S.G. call MD > 1.015			0800 <i>mt</i> 1400 <i>mt</i>	2000 <i>SD</i> 1.015	0330 <i>SD</i> 1.015
Cyclomydril ophthalmic 1gtt each eye repeat in 15 min				1700 <i>mt</i>	
Polysporin ophthalmic Apply to lesional areas on eyelids QID				2000 <i>SD</i>	0000 <i>SD</i>

MEDS NOT GIVEN 1-NPO 2-REFUSED 3-N/V 4-DRS ORDRS 5-OTHER	INJECTION SITES R-RIGHT AB-ABDOMEN L-LEFT U-UPPER D-DELTOID M-MID G-GLUTEAL T-THIGH	SIGNATURE	INITIALS	SIGNATURE	INITIALS
		<i>mpinger</i>	<i>mk</i>	<i>MSHull RN</i>	<i>MT</i>
				<i>SDemich RN</i>	<i>SD</i>

WILLIAMS, LABREA

7/F

Sandell, Sharon R. M.D.

H.601D-1

Page. 1

-117

Date: 06/03/02 Time: 0000		MEDICATION ADMINISTRATION RECORD Medical City Dallas Hospital		Page 2	
WILLIAMS, LABREA H00707472988 H.60 H.601D-1 Sandell, Sharon R., M.D. CHECKED BY: <i>Sally Demuth RN</i>		DIAGNOSIS: RASH FEVER WEIGHT: 39.000kg HEIGHT: 0.4" (1.0) BSA: 0.17 UNIT #: H000826583 ADMIT DATE: 06/02/02 AGE/SEX: 7/F ALLERGIES: NO KNOWN DRUG ALLERGIES NOTES:			
ADMINISTRATION PERIOD: 06/03/02 (0715) - 06/04/02 (0714)		START/STOP: 0715-1514		1515-2314 2315-0714	
***** PRN MEDS * *****					
IBUPROFEN TAB(MOTRIN/ADVIL) DOSE: 400 MG ROUTE: ORAL COMMENTS: PRN T > = 101 UNRESPONSIVE TO TYLENOL USE FOR ADVIL/MOTRIN *** PYXIS ITEM ***		RX #: 06409222	06/02/02 07/02/02	<i>0715MT</i> 2330 SD 0500 SD	
ACETAMINOPHEN BTL(TYLENOL DROPS) DOSE: 580MG=5.8ML ROUTE: ORAL COMMENTS: PRN TEMP > 102 OR PAIN USE FOR TYLENOL DROPS (NOT TO EXCEED 65MG/KG/DAY) *** PYXIS ITEM ***		RX #: 06409958	06/02/02 07/02/02	0810 MK 1315 MT 2100 SD	0030 SD
DIPHENHYDRAMINE HCL VIAL(BENADRYL INJ) DOSE: 25 MG ROUTE: IV COMMENTS: USE FOR BENADRYL *** PYXIS ITEM ***		RX #: 06410866	06/03/02 07/03/02	0810 MK 1315 MT 2100 SD	0030 SD
COLLOIDAL OATMEAL PKT(AVEENO BATH) DOSE: 1 EA ROUTE: TOPICAL COMMENTS: USE FOR AVEENO BATH		RX #: 06410867	06/03/02 07/03/02	0830 MK	
Lacrilube batheyes Q2° if possible				1840 MT 2000 SD	0000 SD
Ibuprofen 400mg pr Q6°				1715 MT	

MEDS NOT GIVEN 1-NPO 2-REFSED 3-N/V 4-DRS ORDRS 5-OTHER	INJECTION SITES R-RIGHT AB-ABDOMEN L-LEFT U-UPPER D-DELTOID M-MID G-GLUTEAL T-THIGH	SIGNATURE	INITIALS	SIGNATURE	INITIALS
		<i>inkingr</i>	<i>mk</i>	<i>ME WURN</i>	<i>MT</i>
				<i>SDemuth RN</i>	<i>SD</i>

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H.601D-1

Page: 2

-20118

Date 06/03/02
Time 0000MEDICATION ADMINISTRATION RECORD
Medical City Dallas Hospital

Page 3

WILLIAMS, LABREA
H00707472988H.60 H.601D-1
Sandell, Sharon R., M.D.

CHECKED BY: _____

DIAGNOSIS: RASH FEVER
WEIGHT: 39.000kg HEIGHT: 5' 0.4" (1.0) BSA: 0.17 UNIT # H000826583
ADMIT DATE: 06/02/02 AGE/SEX: 7/F
ALLERGIES: NO KNOWN DRUG ALLERGIES

NOTES:

ADMINISTRATION PERIOD: 06/03/02 (0715) - 06/04/02 (0714) START/STOP 0715-1514 1515-2314 2315-0714

DEXTROSE 5% 1/2 NS 1000 ML
POTASSIUM ACETATE 20 MEQ
WILLIAMS, LABREA H00707472988

2100 SD 0500 SD

solumedrol 20mg IV Q12

2300 SD

MEDS NOT GIVEN	INJECTION SITES	SIGNATURE	INITIALS	SIGNATURE	INITIALS
1-NPO	R-RIGHT AB-ABDOMEN			Sally Demit	KN SD
2-REFSED	L-LEFT U-UPPER				
3-N/V	D-DELTOID M-MID				
4-DRS ORDRS	G-GLUTEAL				
5-OTHER	T-THIGH				

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H.601D-1

Page 3

119
-21-

Date: 06/04/02 Time: 0000		MEDICATION ADMINISTRATION RECORD Medical City Dallas Hospital		Page: 1	
WILLIAMS, LABREA H00707472988 H.60 H.601D-1 Sandell, Sharon R., M.D. CHECKED BY: <i>Sandell R</i>		DIAGNOSIS: RASH FEVER WEIGHT: 39.000kg HEIGHT: 5' 0 4" (1.0) BSA: 0.17 UNIT #: H000826583 ADMIT DATE: 06/02/02 AGE/SEX: 7/F ALLERGIES: NO KNOWN DRUG ALLERGIES NOTES:			
ADMINISTRATION PERIOD: 06/04/02 (0715) - 06/05/02 (0714)		START/STOP: 0715-1514		1515-2314 2315-0714	
***** SCHEDULED MEDS *****					
✓ NACL 0.9% 32.5 ML CLINDAMYCIN PHOSPHATE (CLEOCIN PHOSPHATE) 390 MG RATE: 65 MLS/HR IV COMMENTS: 12MG/ML (MAX 12MG/ML) VIAL 150MG/ML (NO DILUTION) USE FOR CLEOCIN USE IF PT > 2 YEARS OF AGE		RX #: 06409224 06/02/02 07/02/02		1200 1800 1400mt 1900 0000 0600	
✓ NACL 0.9% 20 ML RANITIDINE (ZANTAC VIAL) 50 MG RATE: 40 MLS/HR IV COMMENTS: 2.5MG/ML (MAX) 1/P// ZANTAC 2.5MG/ML ALIQUOT		RX #: 06409955 06/02/02 07/02/02		1300 2100 1800 1800 0500	
✓ NS 100ML BAG 112 ML ACYCLOVIR SODIUM (ZOVIRAX) 780 MG RATE: 112 MLS/HR IV COMMENTS: USE FOR ZOVIRAX; PREP DATE/TIME **DO NOT REFRIGERATE** STABLE 24 HR POST PREP: MAX CONC = 7mg/ml ##VERIFY ORDER PRIOR TO ADMX##		RX #: 06410997 06/03/02 06/08/02		1200 1800 0000 0600	
✓ BACITRACIN/POLYMYXIN B SULFATE TUBE (POLYSPORIN EYE OINTMENT) DOSE: → APPLY TO LESIONAL AREAS ON EYELIDS ROUTE: OPHTH FREQ: QID @ 08,12,16,20 COMMENTS: /P/ USE FOR POLYSPORIN OPHTH OINT		RX #: 06413858 06/03/02 07/03/02		0800mt 1200mt 1600mt 2000 0000	
✓ LANOLIN/MINERAL OIL/PETROLATUM UD (LACRI-LUBE S.O.P. OINTMENT) DOSE: → APPLY TO BOTH EYES ROUTE: OPHTH FREQ: Q2H COMMENTS: USE FOR LACRI-LUBE APPLY TO BOTH EYES Q 2 HOURS IF POSSIBLE *** PYXIS ITEM ***		RX #: 06413859 06/03/02 07/03/02		0800mt 1000mt 1200mt 1400 1600mt 1800 2000 2200 0000 0200 0400 0600	
MEDS NOT GIVEN 1-NPO 2-REFSED 3-N/V 4-DRS ORDRS 5-OTHER	INJECTION SITES R-RIGHT AB-ABDOMEN L-LEFT U-UPPER D-DELTOID M-MID G-GLUTEAL T-THIGH	SIGNATURE <i>M. J. Miller</i> <i>R. Walton, R</i>	INITIALS <i>MT</i> <i>FW</i>	SIGNATURE	INITIALS

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H.601D-1

Page. 1

-15120

Date: 06/04/02 Time: 0000		MEDICATION ADMINISTRATION RECORD Medical City Dallas Hospital		Page 2
WILLIAMS, LABREA H00707472988 H. 60 H. 601D-1 Sandell, Sharon R., M.D. CHECKED BY: <i>Sally Denil</i>		DIAGNOSIS: RASH FEVER WEIGHT: 39.000kg HEIGHT: 5' 0.4" (1.0) BSA: 0.17 UNIT #: H000826583 ADMIT DATE: 06/02/02 AGE/SEX: 7/F ALLERGIES: NO KNOWN DRUG ALLERGIES NOTES:		
ADMINISTRATION PERIOD: 06/04/02 (0715) - 06/05/02 (0714)		START/STOP: 0715-1514	1515-2314	2315-0714
***** SCHEDULED MEDS *****				
METHYLPREDNISOLONE SOD SUCC VIAL(SOLU-MEDROL) DOSE: 20 MG ROUTE: IV COMMENTS: USE FOR SOLU-MEDROL *** PYXIS ITEM ***		RX #: 06414401	06/03/02 07/03/02	1000 <i>mt</i> 2200
<i>D/C</i>				
clean biopsy site QD \bar{c} tap H ₂ O dress \bar{c} polysporin			1000 <i>mt</i>	
dipstick urine Q6 ^o call MD > 1.015			0900 <i>mt</i> 1500 <i>mt</i>	2100 0300
NS 400ml IV over 1 ^o			1045 <i>mt</i>	
D ^o 1.0W \bar{c} 100ml NaCl & KCL @ 130 <i>ce</i> ^o			1340 <i>mt</i>	
Albumin 25%. 37.5gm IV over 1 ^o			1200 <i>mt</i>	

MEDS NOT GIVEN	INJECTION SITES	SIGNATURE	INITIALS	SIGNATURE	INITIALS
1-NPO 2-REFSED 3-N/V 4-DRS ORDRS 5-OTHER	R-RIGHT AB-ABDOMEN L-LEFT U-UPPER D-DELTOID M-MID G-GLUTEAL T-THIGH	<i>Medil</i>	<i>mt</i>		

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H. 601D-1

Page 2

-1121

Date 06/04/02
Time: 0000MEDICATION ADMINISTRATION RECORD
Medical City Dallas Hospital

Page 3

WILLIAMS, LABREA

H00707472988

H.60 H.601D-1
Sandell, Sharon R., M.D.

DIAGNOSIS: RASH FEVER

WEIGHT: 39.000kg HEIGHT: 0.4" (1.0) BSA: 0.17

UNIT #: H000826583

ADMIT DATE: 06/02/02 AGE/SEX: 7/F

ALLERGIES: NO KNOWN DRUG ALLERGIES

NOTES:

CHECKED BY: *Sally Demirel*

ADMINISTRATION PERIOD: 06/04/02 (0715) - 06/05/02 (0714)

START/STOP | 0715-1514

| 1515-2314

| 2315-0714

***** PRN MEDS * *****

IBUPROFEN TAB(MOTRIN/ADVIL)

RX #: 06409222

DOSE: 400 MG

ROUTE: ORAL

FREQ: PRN Q 6 hours

COMMENTS: PRN T > = 101 UNRESPONSIVE TO TYLENOL

MAY GIVE PER RECTUM

USE FOR ADVIL/MOTRIN

*** PYXIS ITEM ***

06/02/02
07/02/02*1840/ke
PO*

ACETAMINOPHEN BTL(TYLENOL DROPS)

RX #: 06409958

DOSE: 580MG=5.8ML

ROUTE: ORAL

FREQ: PRN Q 4 hours

COMMENTS: PRN TEMP > 102 OR PAIN

USE FOR TYLENOL DROPS

(NOT TO EXCEED 65MG/KG/DAY)

*** PYXIS ITEM ***

06/02/02
07/02/02

DIPHENHYDRAMINE HCL VIAL(BENADRYL INJ)

RX #: 06410866

DOSE: 25 MG

ROUTE: IV

FREQ: PRN Q 4 hours

COMMENTS: USE FOR BENADRYL

*** PYXIS ITEM ***

06/03/02
07/03/02*D/C*

COLLOIDAL OATMEAL PKT(AVEENO BATH)

RX #: 06410867

DOSE: 1 EA

ROUTE: TOPICAL

FREQ: AS NEEDED, (TIMES UNDEFINED)

COMMENTS: USE FOR AVEENO BATH

06/03/02
07/03/02

NON-FORMULARY EACH(NON FORMULARY DRUG)

RX #: 06413695

DOSE: MAGIC THREE MOUTH WASH; DOSE=4 ML

ROUTE: MISC

FREQ: PRN Q 6 hours

COMMENTS: MAALOX; BENADRYL; VISCOUS LIDOCAINE 1:1:1 (SEND 180 ML)

DOSE=4 ML **SWISH/SPIT**

06/03/02
07/03/02*Fentanyl 15-30 mcg IV Q1P PRN**1110Mth
30mcg**2000
30mcg
1520Mth
30mcg
1825Mth
30mcg*

MEDS NOT GIVEN	INJECTION SITES	SIGNATURE	INITIALS	SIGNATURE	INITIALS
1-NPO	R-RIGHT AB-ABDOMEN	<i>M. Demirel</i>	<i>MH</i>	<i>S. Demirel</i>	<i>SD</i>
2-REFSED	L-LEFT U-UPPER				
3-N/V	D-DELTOID M-MID				
4-DRS ORDRS	G-GLUTEAL				
5-OTHER	T-THIGH				

WILLIAMS, LABREA

7/F

Sandell, Sharon R., M.D.

H.601D-1

Page: 3

-1122

Page: 4

Memorandum of Transfer

Section A (To Be Filled Out by and at Transferring Hospital)	
1. Name of Hospital: <u>THE CT Medical Ctr.</u> Address: <u>7777 Forest Ln</u> <u>Dallas, TX 75230</u> Telephone Number: <u>(214) 566-7000</u>	7. Transferring physician's signature or signature of hospital staff acting under physician's orders: <u>[Signature]</u> Date: <u>6-4-02</u> Time: _____ Telephone Number: <u>(214) 566-1717</u> Address: <u>7777 Forest Ln</u> <u>Dallas, TX 75230</u>
2. Patient Information (if known) Patient's full name: <u>Labrea Williams</u> Address: <u>3201 Manderhill Ln #208</u> <u>Dallas, TX 75231</u> Telephone Number: <u>(214) 360-0631</u> Sex: <input type="checkbox"/> M <input checked="" type="checkbox"/> F Age: <u>34</u> National Origin: _____ Race: <u>HH</u> Religion: <u>RapFist</u> Physical Handicap: _____	8. Accepting hospital secured by transferring hospital Date: <u>6/4/02</u> Time: <u>1700</u> Name of accepting hospital administration person: <u>Kathleen Spears</u>
3. Next of kin information (if known) Next of kin: <u>Lascandra Williams</u> Address: <u>3201 Manderhill</u> <u>#09 Dallas TX 75231</u> Telephone Number: <u>(214) 360-0631</u> Next of kin notified? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9. Transferring hospital administration signature: <u>Tanya V. R.</u> Title: <u>NIS/Care Mgr.</u> Date: <u>6/4/02</u> Time: <u>1815</u>
4. Date of arrival: <u>6-2-02</u> Time: <u>0530</u>	10. Type of vehicle and company used: <u>AMR 214) 353-7600</u> Type of equipment and/or personnel needed: _____
5. Initial contact with receiving hospital: Date: <u>6-4-02</u> Time: <u>1145</u> Name of contact person at receiving hospital: <u>Kathleen Spears</u>	11. Patient transported to: <u>Portland Memorial</u> <u>Hospital</u> (facility)
6. Accepting physician secured by transferring physician: Date: <u>6-4-02</u> Time: <u>1145</u> Name of accepting physician: <u>Dr. Hackett</u>	12. Diagnosis: <u>Stricken - Unknown</u>
13. Attachments X-Ray _____ Physician Progress Notes <input checked="" type="checkbox"/> Lab Reports <input checked="" type="checkbox"/> Nurse Progress Notes <input checked="" type="checkbox"/> H & P <input checked="" type="checkbox"/> Medication Record <input checked="" type="checkbox"/> Other (specify): _____	
Section B (To Be Filled Out by and at Receiving Hospital)	
1. Name of Hospital: _____ Address: _____ Telephone Number: () _____	4. Receiving physician assuming patient responsibility: Date: _____ Time: _____ Receiving Physician's Signature: _____ Address: _____ Telephone Number: () _____
2. Date of arrival: _____ Time: _____	5. If response to transfer request was delayed beyond thirty (30) minutes, document the reason(s) for the delay, including any time extensions agreed to by transferring hospital. Use additional sheet, if necessary. _____ _____
3. Hospital Administration Signature: _____ Date: _____ Title: _____	

INSTRUCTIONS: The transferring hospital completes Section A of this memorandum, sends the original (white) page plus the attachments required by section 11-2.9. of the Hospital Licensing Standards with the patient, and retains the second (yellow) copy. The receiving hospital completes Section B and retains the form. Both the transferring and receiving hospitals must file the memorandum separately from the patient's medical record and in a manner which will facilitate its inspection by the Texas Department of Health.

**Medical City Dallas
Hospital**

Memorandum of Transfer

Form # 0919125 Dept. All Nursing (Rev.04/00)

White: Receiving Hospital

Patient Identification

Medical City Dallas Hospital

WILLIAMS, LABREA

H00707472988 MR#: H000826583 6/2/2002

DOB: 07/20/94 7/F Sandell, Sharon R., M.D.

Yellow: Medical Record

-73124

N5402

Patient Name	Medical Record No.	Date	Time
--------------	--------------------	------	------

Physician Certification for Transfer

I, James Hackett, (physician ordering transfer), certify that the medical benefits reasonably expected from the provision of appropriate medical treatment at Portland Burn Unit (receiving facility) outweigh the risks to the individual's medical condition from effecting this transfer, based upon the information available at the time of transfer.

Summary of Benefits of Transfer Care for debridement related to SVS

Risks of Transfer auto wreck, lack of direct access

Risks if the Individual is Not Transferred maximize skin care / care

Physician present at time transfer order was given: yes ☒ yes ☐ no

Physician Present [Signature] (physician's signature) Date 6-4-02 Time 1810

Physician Not Present: _____ Date and Time Order Received _____

Qualified Medical Person (QMP) Receiving Order to Transfer: _____ (print name) _____ (title)

QMP Signature: _____ Date _____ Time _____

Physician's Signature [Signature] Date 6-4-02 Time 1810

Patient Consent for Transfer

I acknowledge that my medical condition has been evaluated and explained to me by the physician or other qualified medical person and/or my attending physician who has recommended that I be transferred to the service of Dr. Hackett at Portland. The potential benefits of such transfer, the potential risks associated with transfer and the probable risks of not being transferred have been explained to me and I fully understand them. With this knowledge and understanding, I agree and consent to be transferred.

I have been informed of my rights regarding examination, treatment, and transfer.

X [Signature] mother
 Signature of patient or legally responsible individual signing on patient's behalf
 Relationship to patient

[Signature] 6-4-02 18:30
 Witness
 Date and Time

The above signature includes understanding and agreement to transfer and release of medical records.

PATIENT IDENTIFICATION

Medical City Dallas Hospital
WILLIAMS, LABREA
 H00707472988 MR#: H000826583 6/2/2002
 DOB: 07/20/94 7/F Sandell, Sharon R., M.D.

Patient Transfer Certification

Physician Certification

Patient Consent for Transfer

N5402 07/98 (RC# 0258932)

CHART

-74¹²⁵

Receiving Facility Name & Address Parkland Memorial Hospital			Telephone 214/591-8108	
Patient Last Name Williams	First Labrea	Middle	Transfer Date 6-4-02	Departure Time
Accepting Physician in new facility Dr. Hackett			Primary Diagnosis Steven Johnsons	Secondary Diagnosis
Allergies: Food / Drug / Latex			PL aware <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Arrival Time Scheduled

Transfer Orders	
Code Status Full	PT/OT/ST
Medications Zantac 50mg IV q 8	Potential for Rehab <input checked="" type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor
polypharmacy on ophthalmic to lesions on eye	Estimated Length of Stay
lacrilube ointment to eyes q 2	D/C Plan / Goals wound care hydration
Fentanyl 15-30 mg IV q 1 prn	Nutrition CL
Odell	Activity c assistance
	Other Treatments (Dressings, Respiratory, Laboratory, etc.) IVF
Mode of Transport	
I certify that SNF services are required to be given on an inpatient basis because of the patient's need for skilled nursing care on a continuing basis for the condition(s) for which he/she was receiving inpatient hospital services prior to his/her transfer to the SNF.	
Transferring Physician Signature (or Designee) <i>[Signature]</i>	Date 6-4-02 Time 1810
Transferring Physician Address and Phone MCH 972 566 6717	

Medical Information (Check Attachments)	
<input type="checkbox"/> Advance Directive	<input type="checkbox"/> Interdisciplinary Progress Notes
<input type="checkbox"/> Hospital Face Sheet (must attach)	<input type="checkbox"/> Most Recent Labs/Radiology Reports
<input type="checkbox"/> Psychosocial Assessment	<input type="checkbox"/> State Required Regulatory Forms
<input type="checkbox"/> History and Physical	<input type="checkbox"/> Other (specify) _____
<input type="checkbox"/> Transfer or Discharge Summary (Physician)	
<input type="checkbox"/> Physician Consults (specify) _____	
<input type="checkbox"/> Operative Notes (specify) _____	

See folder enclosed

Ambulance Authorization	
I understand that I may use these or any service I desire. I choose to use the service noted below and understand that I am responsible for cost incurred that are not covered by my insurance.	

Patient/Parent Signature <i>Sandra Barber-Maddox</i>	Date 6/1/02
Medical City Dallas Hospital	Phone 214 566 6717

Patient Transfer Summary
Inter Agency Referral

Medical City Dallas Hospital
WILLIAMS, LABREA
H00707472988 MR#: H000826583 6/2/2002
DOB: 07/20/94 7/F Sandell, Sharon R., M.D.

WHITE - RECEIVING AGENT YELLOW - CHART PINK - PHYSICIAN

-75126

APPENDIX 3

219

Institute of Neurologic Disease and Stroke of the National Institute of Health, a dermatology residency at Harvard Medical School-Massachusetts General Hospital, and a fellowship at the Harvard Center for Community Health and Medical Care. Since 1976 I have been a member of the full time faculty of Harvard Medical School. Currently, I serve as the Carl J. Herzog Professor of Dermatology at Harvard Medical School and the Chief of Dermatology at the Beth Israel Deaconess Medical Center, which is a principle teaching hospital of Harvard Medical School. I am also on the staff of the Brigham and Womens and Childrens Hospital of Boston and the Dana Farber Cancer Institute and Harvard Cancer Center. I am the author of more than 135 peer-reviewed publications and 130 book chapters, editorials and reviews and other medical publications, many of which concern adverse reactions to medications, including articles on this topic in the *New England Journal of Medicine*, *JAMA*, and the *Lancet*. My publications have been cited more than 5000 times in the peer-reviewed literature.

2. Among my other experience and research pertinent to the opinions I provide in this declaration are my developing and serving as principal investigator for a specialty-based system for reporting cutaneous adverse reactions and as one of the founders and senior investigators of the international SJS/TEN study. I have given invited lectures concerning adverse drug reactions on three continents and was invited to provide a staff seminar for the USFDA concerning drug-induced skin eruptions. I have also served as the Chairman for the USP Advisory Panel on Dermatology. I have extensive experience working with the USFDA including more than 10 years as a member of the Dermatologic and Ophthalmic Drug Advisory Committee including a four-year term as Chairman of that committee. Currently, I serve as consultant to the USFDA.

3. With regard to the case of LaBrea Williams, the history taken from the mother, LaSandra Madden, of this seven year-old African American girl revealed that she awoke on the morning of 6/1/02 with multiple facial lesions including blistering lesions of the right cheek. Her other skin lesions included those of the other cheek and forehead. She also had generalized malaise. Before 4:00 p.m., she complained of generalized itching of the skin, which is often a symptom of a generalized skin eruption which is noted before the rash is apparent. She was first treated with Benadryl. After the child's mother took her temperature (104°F) she was given Advil. "At that time the blisters began to appear on the Child's lips." (see Medical City Note 6/2/02 dictation of 5:50 a.m. by Dr. Sandell). The child also reported sore throat and had vomited. When examined between 4:00 a.m. and 5:50 a.m. on 6/2/02, she was noted to have fever, a bullous appearing fluid-filled lesion on her right cheek, multiple small blistering (and swelling) of her lips, multiple papular lesions on a red base of the face, neck, torso, arms, legs, back, (i.e. generalized) as well as erythema of the palms. These areas are reported to be pruritic as was reported prior to 4:00 p.m. on 6/1/04. She also had a red throat. She was admitted to Medical City.

4. Clearly, LaBrea Williams's disease process which included fever, blistering, pruritic rash described before 6:00 a.m. on June 2, 2002, at Medical City represents natural progression of the same disease process reported by the mother prior to 4:00 p.m. on June 1, 2002, when LaBrea first took Advil, which as described by her mother included fever, generalized pruritus (as the first symptom of her not yet apparent generalized red rash), and blistering).

5. By June 2, 2002, the rash was characterized as vesicular and on June 3, 2002, a punch biopsy was performed, which was described as showing "subepidermal vesicle with

superficial perivascular and interstitial dermatitis consistent with erythema multiforme.” (Specimen # DL: M02:7498). In the subsequent weeks, LaBrea Williams developed progression of her eruption with increased blistering. Given her fever, blistering rash and mucosal involvement, her condition has features most consistent with both severe Erythema Multiforme Major, Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). Although these diseases are rare, in those rare cases that occur in children, cases with features of all three diagnoses are sometimes seen (see Auquier-Durant, *A. Arch Dermatol.* 2002; 138: 1019-1024). Whichever diagnostic term(s) are given in this case with features of both conditions, it is clear that her condition had begun on or prior to awakening on June 1, 2002, which is prior to her first use of Advil. Given that her condition rash, fever, pruritus began before her first use of Advil and for at least two signs/symptoms (rash, pruritus) before her use of Benadryl and the biopsy results and her clinical findings and the absence of any other known exposures to drugs, it is most likely that her condition was an immunologic response to an infectious agent, possibly herpes simplex given her clinical presentation and her paternal grandmother’s report that LaBrea had a history of cold sores. Of course, an immunologic reaction to a drug, chemical, environmental agent, or even a food preservative to which LaBrea was exposed prior to the morning of June 1, 2002, cannot be excluded.

6. Simply put, by clinical criteria, by criteria used in credible epidemiologic studies, and by the typical criteria and algorithms used for assessing the cause of severe skin reactions, the onset of LaBrea Williams’s febrile mucocutaneous illness was the morning of June 1, 2002, prior to use of ibuprofen (see Roujeau and Stern, Roujeau J C et al *NEJM* 1994 and 1995 respectively). Among the compelling reasons for dating the onset of LaBrea Williams’s febrile

mucocutaneous eruption, which eventually evolved into her more generalized blistering eruption are the following:

- 1) she had fever before taking ibuprofen;
- 2) she had skin lesions including blistering lesions of the face before she took ibuprofen;
- 3) she had generalized malaise before taking ibuprofen; and
- 4) and she had generalized itching before taking ibuprofen.

7. Taken together, these four facts and other aspects of her clinical history all indicate that her blistering illness began before she took ibuprofen and was not a result of its use.

8. The signs and symptoms she had before taking ibuprofen are among the most frequent presenting signs and symptoms of erythema multiforme major (EMM), Stevens-Johnson-Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). Taken together, the onset of LaBrea Williams's illness was prior to her use of ibuprofen.

9. The initial eruption of EMM/SJS/TEN is often a widespread "morbilliform" eruption exactly as observed in Dr. Sandell's early morning 6/2/02 admitting note, in which she describes an intensely itchy widespread rash of red bumps. In persons with substantial skin pigmentation, the initial pink macular (flat) phase of this eruption is often not observed, particularly in a child with fever where flushing is often observed. However, her pruritus which began before her first use of ibuprofen on 6/2/02 and continued, was like her rash increasing in intensity when her rash was observed early on 6/2/02 to be revised red and bumpy with the careful exam by Dr. Sandell.

10. Even if one accepts the illogical and flawed argument of Plaintiff's experts, that her febrile mucocutaneous blistering disease began early on June 2, 2002 within, at the longest,

14 hours of her first use of ibuprofen, our knowledge of natural history and pathophysiology of drug-induced EMM/SJS/TEN exclude ibuprofen as the cause of LaBrea Williams's illness, with high medical certainty.

11. When due to drugs, chemicals, or other "antigens" such as viruses EMM/SJS/TEN are a result of "delayed" type hypersensitivity reaction which requires "sensitization" before the reaction can be elicited (brought out) by the antigen. Sensitization to a new "antigen" typically requires 5 to 15 days and cannot occur in a matter of hours. In her deposition, LaBrea Williams's mother stated LaBrea Williams had not used ibuprofen before, and one previous medical record three years prior identifies one previous exposure to ibuprofen. Hence, even according to the Plaintiff's experts flawed argument that the patient's illness began early in the morning of 6/2/02, insufficient time had occurred for sensitization to occur and ibuprofen to cause the eruption.

12. Even if contrary to the facts presented in the record, an argument is made that LaBrea Williams had used and tolerated ibuprofen before, insufficient time had elapsed from her use on the afternoon of 6/1/02 to the early morning of 6/2/02 for even a previously sensitized individual to elicit the signs and symptoms described on 6/2/02. In fact, these 6/2/02 signs and symptoms represented the progression of LaBrea Williams's illness whose first signs and symptoms were manifest early on 6/1/02, well before she used ibuprofen.

13. Although TEN is most often a drug-induced illness, even in careful studies the attributable fraction (proportion due to drugs) is between 60 and 80% in adult populations. For EMM, SJS, and children with TEN, the proportion of cases attributable to drugs is even lower. Many of these cases are due to immunologic reactions to infectious illnesses such as virus. For LaBrea Williams, an immunologic reaction to an infectious illness or unknown environmental

exposure are the likely cause of her condition that began June 1, 2002. With an extremely high degree of medical certainty, ibuprofen can be excluded as the cause of her febrile mucocutaneous blistering eruption.

14. SJS and TEN are very rare conditions with about 2 to 5 cases occurring in a million persons in a year from all causes. The risk of SJS/TEN in association with ibuprofen is less than one in a million for persons that have used the drug for one week.

15. The overwhelming evidence is that there is a very low and comparable risk of SJS/TEN with acetaminophen and ibuprofen.

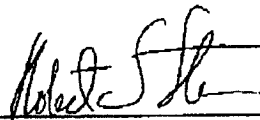
16. For example, in the international SJS/TEN Study, the risks of SJS/TEN associated with ibuprofen and acetaminophen are statistically the same. In fact, the point estimate for the risk of associated with acetaminophen is higher than that for ibuprofen (see Roujeau, et. al. *NEJM*, 1995 and Mockenhaupt, *J. Rheumatology*, 2003). I am an author of both of these papers and familiar with these results. I have spoken with Dr. Roujeau and confirmed that the additional data collected as part of the Euroscar study confirm that the risks of SJS/TEN associated with ibuprofen and acetaminophen are comparable and barely reach statistical significance.

17. The Plaintiff's experts place great emphasis on spontaneous reports indicating a high-risk of EM/SJS/TEN in association with ibuprofen use. First, the FDA Adverse Event Reporting System (AERS) is meant to be used for hypothesis generation and signaling of possible safety concerns with medications. Data from this system is not as robust as a well designed and executed case control study such as the international SCAR study which demonstrated comparable and low risks of EM/SJS/TEN in association with ibuprofen and acetaminophen use (see above). Secondly, a review of the AERS data from the fourth quarter of

1997 to the first quarter of 2004 indicates that ibuprofen was less than half as often reported as a suspect drug for EM/SJS/TEN as acetaminophen (78 reports with ibuprofen as a suspect drug for EM/SJS/TEN vs 200 reports for acetaminophen). Further, reports with ibuprofen, a very widely-used medicine, as a suspect drug for EM/SJS/TEN represent less than one half of one percent of the 16,271 drugs listed as "suspect" causes of EM/SJS/TEN, whereas acetaminophen reports comprised 1.2 percent of all drugs reported to AERS as suspect cause of EM/SJS/TEN. Third, because ibuprofen is often used to treat the first symptoms of EM/SJS/TEN (fever and malaise), as was the case in LaBrea Williams's illness, spontaneous reports are particularly subject to inappropriate causality assignment for ibuprofen, as the full signs and symptoms of an ongoing EM/SJS/TEN reaction, due to another cause, may not be manifest until after ibuprofen has been used to treat the first symptoms of EM/SJS/TEN.

18. In summary, there is no credible evidence that acetaminophen is less likely to cause EM/SJS/TEN than ibuprofen. Both of these medications are rare causes of these reactions

I declare under penalty of perjury that the foregoing is true and correct. Executed on April 18, 2005.



Robert S. Stern, M.D.

Exhibit 1

CURRICULUM VITAE

April 18, 2005

Name: Robert Stuart Stern

Address: 39 Clinton Road
Brookline, MA 02445

Place of Birth: New Haven, Connecticut

Education:

1966 A.B.	Harvard College (<u>magna cum laude</u>)
1970 M.D.	Yale University School of Medicine

Postdoctoral Training:

Internship and Residencies:

1970-1971	Intern in Internal Medicine, The Mount Sinai Hospital, New York, NY
1973-1976	Resident in Dermatology, Harvard Medical School, Massachusetts General Hospital, Boston, MA

Research Fellowships:

1971-1973	Research Associate, Clinical Epidemiology and Genetics, National Institute of Neurologic Diseases and Stroke, National Institutes of Health, Bethesda, MD
1974-1975	Research Fellow, Department of Dermatology, Massachusetts General Hospital, Harvard Medical School, Boston, MA
1975-1976	Fellow, Harvard Center for Community Health and Medical Care, Harvard Medical School, Boston, MA

Licensure and Certification:

1974	Massachusetts License Certificate No. 36176
1977	American Board of Dermatology
1987	Fellow, American College of Epidemiology

Academic Appointments:

1973-1976	Clinical Fellow in Dermatology, Harvard Medical School
1976-1979	Instructor in Dermatology, Harvard Medical School
1976-1983	Member, Center for the Analysis of Health Practice, Harvard School of Public Health
1979-1984	Assistant Professor of Dermatology, Harvard Medical School
1983-1990	Member, Institute for Health Research, Harvard School of Public Health
1984-1997	Associate Professor of Dermatology, Harvard Medical School
1997-2000	Professor of Dermatology, Harvard Medical School
2000-	Carl J. Herzog, Professor of Dermatology, Harvard Medical School

Hospital Appointments:

1976-1978	Associate in Dermatology, Beth Israel Hospital, Boston
1976-1978	Consultant in Dermatology, Boston Hospital for Women, Boston
1976-1980	Assistant in Dermatology, Children's Hospital Medical Center, Boston
1976-1979	Clinical Assistant in Dermatology, Massachusetts General Hospital, Boston
1977-	Consultant in Division of Medical Oncology, Sidney Farber Cancer Institute, Boston
1978-1982	Junior Associate in Medicine (Dermatology), Peter Bent Brigham Hospital, Boston
1978-1979	Assistant Dermatologist, Beth Israel Hospital, Boston
1979-1983	Associate Dermatologist, Beth Israel Hospital, Boston
1979-	Clinical Associate in Dermatology, Massachusetts General Hospital, Boston
1980-	Associate in Dermatology, Children's Hospital Medical Center, Boston
1982-	Associate Physician in Medicine (Dermatology), Brigham & Women's Hospital, Boston
1983-2000	Dermatologist, Beth Israel Hospital, Boston
1999-	Member, Harvard Cancer Center
1999-	Consultant, Children's Hospital Medical Center, Boston
2000-	Dermatologist-In-Chief, Beth Israel Deaconess Medical Center
2001-2003	Senior Consultant, Massachusetts General Hospital

Other Professional Positions and Major Visiting Appointments:

1971-1973	Senior Assistant Surgeon (1971-72), Surgeon (1972-73), U.S. Public Health Service, National Institutes of Health, Bethesda, MD
1971-1973	Consultant, Health Services Industries Committee, Cost of Living

	Council, Executive Office of the President
1976-1977	Research Fellowship Recipient, Dermatology Foundation
1979	Johns Hopkins Medical School
1984	New York University School of Medicine
1984-1992	Associate Editor, Archives of Dermatology
1985	University of Puerto Rico Medical School
1987	Johns Hopkins Medical School
1989	Dartmouth Medical School
1990-	Reviewer, Psoriasis: Professional Educational Materials: An Annotated Bibliography. National Institute of Musculoskeletal and Skin Diseases.
1990-	Reviewer, The World Book Encyclopedia, Chicago, IL: World Book Co., 1990.
1992-2000	Co-Editor, Archives of Dermatology
1993-2000	Editor, Medical and Surgical Dermatology: A Critical Guide To The Literature
1999-	Contributing Editor, Harvard Medical School Family Health Guide
2000-	Section Editor, Up to Date
2000-	Contributing Editor, Harvard Medical School/Intellihealth

Awards and Honors:

1966	Phi Beta Kappa, Harvard College
1966	Woodrow Wilson Scholar
1972	Letter of Commendation, The White House
1980	International Travel Award, French Society of Dermatology
1985	Milton Fund Fellowship

Major Committee Assignments:

National and Regional:

1981-1985	Advisory Panel on Dermatology, Member, U.S. Pharmacopeial Convention, Inc.
1983	Committee on Causes and Effects of Changes in Stratospheric Ozone: 1983 Update, Member, National Academy of Science
1983-1989	Project Advisory Committee and Safety and Data Monitoring Committee, Member, Beta Carotene as a Chemopreventive in Skin Cancer (National Institutes of Health funded multicenter study)
1984-1988	Dermatologic Drugs Advisory Committee, Member, U.S. Food and Drug Administration
1985	Committee to Evaluate Fansidar, Consultant, National Centers for Disease Control

1985-2000 General Committee of Revision, Member, U.S. Pharmacopeial Convention, Inc.

1985-2000 Advisory Panel on Dermatology, Chairman, U.S. Pharmacopeial Convention, Inc.

1986-1996 National Epidermolysis Bullosa Registry, Consultant

1988-1995 Executive Committee of Revision, Member, U.S. Pharmacopeial Convention, Inc.

1988-2003 Accutane Use Study, Slone Epidemiology Unit, Member, Advisory Committee, Boston University

1992-2000 Member, Steering Committee of the National EB Registry

1995-2000 Drug Information Executive Committee, Member, U.S. Pharmacopeial Convention, Inc.

1995-2002 National Skin Diseases Data Workgroup, Member, National Institutes of Health

1999-2000 U.S. Food and Drug Administration, Dermatologic and Ophthalmic Drug Advisory Committee

1999 Member, Institute of Medicine, Committee on Medicare Coverage Extensions

1999- Member, Medical Advisory Board, National Psoriasis Foundation

1999- Member, Board of Directors, The Photomedicine Society

2000 Ad Hoc Reviewer, National Institute of Arthritis Musculoskeletal and Skin Disease

2002- Chairman, US Food and Drug Administration, Dermatologic Drugs Advisory Committee

2001-2004

2005- Consultant to US Food and Drug Administration

Hospital:

1974-1976 Representative for Dermatology, Massachusetts General Hospital House Officers Committee

1982-1987 Pharmacy and Therapeutics Committee, Beth Israel Hospital

1988- Committee on Graduate Medical Education, Beth Israel Hospital Research Operations Committee, Beth Israel Hospital

Director, Residency Training in Dermatology, Beth Israel Hospital

2000- Chairman, Department of Dermatology, Beth Israel Deaconess Medical Center

Departmental:

1980- Faculty Advisor

1983-1987 Resident Selection Committee

1984- Executive Committee

1988- Chairman, Clinical Research Committee

Medical School:

1993- Task Force on Ambulatory Education
 1994- Committee on Ambulatory Education Self Assessment
 1996-2000 Council for Research, Harvard Medical School - Beth Israel
 Deaconess Medical Center, Foundation for Research and Education
 2003- Member, Subcommittee of Professors, Harvard Medical School
 Memberships, Offices and Committee Assignments in Professional Societies:

1973- Society for Investigative Dermatology
 1976- American Academy of Dermatology
 1978-1981 Co-chairman, Committee on Therapeutics and Cosmetics, American
 Academy of Dermatology
 1979- Dermatology Foundation
 1979- New England Dermatologic Society
 1979- Boston Dermatological Society
 1980- American Society for Photobiology
 1980-1986 Scientific Director, Adverse Drug Reaction Reporting System,
 American Academy of Dermatology
 1980- American Society for Epidemiologic Research
 1980-1983 Program Committee, Boston Dermatological Club
 1981-1983 Chairman, Committee on Governmental Relations, American
 Academy of Dermatology
 1981-1983 Council on Government Liaison, American Academy of
 Dermatology
 1981-1988 American Society for Laser Medicine and Surgery
 1981-1984 Committee on Regulatory Affairs, American Academy of
 Dermatology
 1982-1985 Task Force on Psoriasis, American Academy of Dermatology
 1983-1987 Member, American Academy of Epidemiology
 1983-1986 Task Force on Dermatology/Pharmacy, American Academy of
 Dermatology
 1983-1986 Task Force on Manpower, American Academy of Dermatology
 1984- Council of Biology Editors
 1984-1987 Committee on Diagnostic-Related Groups, American Academy of
 Dermatology
 1985- Massachusetts Medical Society
 1986-1989 Member, Committee on Psoriasis, American Academy of
 Dermatology
 1986-1989 Chairman, Task Force on Relative Value Scales, American
 Academy of Dermatology
 1986-1989 Chairman, Task Force on Dermatology/Pharmacy, American
 Academy of Dermatology
 1986-1989 Committee on Psoriasis, American Academy of Dermatology
 1986-1987 Chairman, Publications Committee, American Society for Laser
 Medicine and Surgery
 1989-1993 Consultant, Seventh Edition, American Medical Association Drug

Evaluations

1989-1992	Member, Task Force on Federal Drug Administration Liaison, American Academy of Dermatology
1990-1992	Member, Task Force on Guidelines for Phototherapy, American Academy of Dermatology
1991-1993	Member, Task Force on Accutane, American Academy of Dermatology
1991-	Member, American Dermatological Association
1991-	Abstract Reviewer, Society of Investigative Dermatology
1994	Member, Scientific Committee, Congress on Cutaneous Drug Reactions, Paris
1995	Scientific Board, First International Conference on Epidemiology: Causes and Prevention of Skin Diseases, Marseille, France
1995	Scientific Program Committee, Photocarcinogenesis: Mechanisms, Models and Human Health Implications
1995-1997	Scientific Consultant, Multicenter Study (Italy) to assess efficacy of cimetidine in the treatment of psoriasis
1998	Scientific Committee, Second International Meeting on Epidemiology and Prevention of Skin Diseases
1998-2002	Steering Committee of the Cutaneous ADR-group
1999-2005	Medical Advisory Board, National Psoriasis Foundation
2000-2002	President, International Dermatoepidemiology Association
2001-	Board Member, Photomedicine Society

Editorial Boards:

1982-1990	Section Editor, Year Book of Dermatology
1983-	Archives of Dermatology (Associate Editor 1984-1992, Co-editor 1992 - present)
1988-	Journal of Pharmacoepidemiology
1990-2000	Photodermatology, Photoimmunology, and Photomedicine
1993-2000	Section Editor, Clinical Pharmacology, Archives of Dermatology
1993-2000	Editor, Medical and Surgical Dermatology
1995-2000	International Editorial Board, Journal of Cutaneous Medicine and Surgery
2004-	Photodermatology, Photoimmunology, and Photomedicine.

Major Research Interests:

1. Epidemiology of Dermatologic Disease
2. Psoriasis
3. Adverse Drug Reactions
4. Health Services Research
5. Photobiology

Research Funding Information

<u>Past:</u>	1980-1986	USFDA, A specialty based adverse reaction PI reporting system (Scientific)	
	1983-1993	NIH, Photochemotherapy Follow-Up Study Assessment of risks and benefits of oral psoralen photochemotherapy for psoriasis	PI
	1986-1987	Milton Fund, Resource use by HMO and non-HMO patients	PI
	1988-1990	Massachusetts Fund for Cooperative Innovation, Effects of socioeconomic status on cost of care and access to care.	Co-PI
	1987-1992	Roche Laboratories, Etretinate Follow-Up Study Assessment of safety and efficacy of etretinate therapy for psoriasis, a multicenter 5-year 1,000 person cohort study.	PI
	1992-1994	Roche Laboratories, Epidemiology of Acne Database studies and cooperative population based study with the Mayo Clinic	PI
	1993-1995	USFDA, Ultraviolet Therapy Use Among HIV Infected Persons Assessment of ultraviolet radiation in the treatment of cutaneous disease in HIV-infected persons	
	1996-1998	NIH, RO1 CA76174 - O1A1 Genetic alterations in PUVA induced skin cancers	Co-PI
	1999-2005	NIH, Follow-Up Study of Patients Treated with Oral Psoralen Photochemotherapy Assessment of long-term risk of oral psoralen photochemotherapy	PI
	2000-2001	Searle, Epidemiologic Assessment of Risk of SJS and TEN in association with NSAIDs	

Principal Clinical and Hospital Service Responsibilities:

1976-	Attending Physician, Dermatology Clinic, Beth Israel Hospital, once weekly
1976-	Attending Physician, Consultation Service, Beth Israel Hospital, three times per month
1978-	Director, Phototherapy Center, Beth Israel Hospital
2000-	Dermatologist-In-Chief, Beth Israel Deaconess Medical Center

Self Report of Teaching:

Local Contributions:

Harvard Medical School Undergraduate Courses:

1976-	Preceptor, Dermatology Clinical Clerkship, Multiple Months each year
1977-1985	Section Leader, Pathophysiology of the Skin
1985-2000	Lecturer, Pathophysiology of the Skin (most years)
1985-	Supervisor, Medical student research projects (1-2 Harvard Medical School students/yearly)
1991-1993	Preceptor for Dermatology, Introduction to Clinical Medicine
1991-	Preceptor, Ambulatory Care Clerkships
2000-	Senior Institute Scholar, The Carl J. Shapiro Institute for Education and Research at Harvard Medical School

Department of Dermatology, Harvard Medical School:

1976-	Dermatology Literature Review, Dermatology Residency Training Program (1-2 times/monthly)
1976-	Combined Longwood Avenue Area Dermatology Grand Rounds (1-2 months/yearly)
1976-	Dermatology Grand Rounds, Massachusetts General Hospital (1-3 times/yearly)
1976-	Faculty Advisor, Dermatology Residency Training Program (1 resident per year)
1980-	Clinical Fellowship Program, Beth Israel Hospital (0-2 fellows/yearly)
1990	Lecturer, Collaborative Course on Biology of the Skin, Boston, MA

Beth Israel Hospital Lectures and Rounds:

1976 - Lecturer, Medical Grand Rounds
Presentations to Beth Israel Hospital Departments of Medicine
and Surgery including Rounds from conferences, lecture series,
Emergency Ward Conferences

Harvard Medical School Postgraduate Courses:

1978-1982 Faculty, Adolescent Medicine Course
Management of Medical and Surgical Emergencies
1979-1981 Faculty, Argon Laser and Cutaneous Vascular Surgery
1983 Co-Director, Cutaneous Laser Therapy
1985 Co-Director, Cutaneous Laser Therapy
1989 Faculty, Update in Cutaneous Laser Surgery
1994 Lecturer, Update in Internal Medicine
1995 Lecturer, Dermatology for the Practicing Physician

Harvard College:

1976-1979 Premedical Advisor, Kirkland House, Harvard College
1983 Lecturer, Harvard College Biology Seminar

Harvard School of Public Health:

1976-2000 Lecturer, Courses, symposia, workshops on health services
research and occupational dermatology
1977-1997 Postgraduate Courses in Occupational Medicine
1977-1980 Participant, Faculty Seminar on Health Care Technology,
Harvard School of Public Health
1979-1989 Consultant for Health Hazard Evaluations, Harvard School of
Public Health, Occupational Health Program
1980 Lecturer, Seminar on Decision Analysis
1986 Faculty, Postgraduate Course on Medical Decision-Making

Other Local Hospitals and Medical Schools:

1976- Medical Grand Rounds, Cambridge Hospital
1976- Medical Grand Rounds, Veterans Administration Hospital
1976- Dermatology Grand Rounds, Tufts University/Boston University
Schools of Medicine

1977	Lecturer, Winchester Hospital
1977	Lecturer, Cooley-Dickenson Hospital (Northampton, MA)
1977	Lecturer, Cable Memorial Hospital (Ipswich, MA)
1977	Lecturer, Noble Hospital (Westfield, MA)
1977	Lecturer, Hale Hospital (Haverhill, MA)
1977	Lecturer, Harrington Memorial Hospital (Southbridge, MA)
1981	Resident Education Lecture Series, Memorial Hospital, University of Massachusetts Medical School, Worcester
1982-	Lecturer, Postgraduate Course on Industrial Medicine, Boston University School of Nursing
1995-	Lecturer, Core Curriculum in Primary Care, Boston

Regional, National, and International Contributions:

1976	Dermatology Grand Rounds, Johns Hopkins Medical Institute
1977	Lecturer, UCLA School of Medicine
1978-	American Academy of Dermatology Annual Meetings (or talk(s) at each meeting related to psoriasis, epidemiology, and drug reactions)
1978	Society of Investigative Dermatology Annual Meeting, Participation in workshops and presentation of scientific papers
1979	Lecturer, Course on Empiric Risk of Genetic Disease, American Public Health Association, Annual Meeting
1979	Consultant to Dermatology Advisory Panel, Food and Drug Administration (multiple meetings)
1980	Invited Presentation and Travel Fellowship, VIII International Photobiology Conference, Strasbourg, France
1981	Lecturer, International Symposium on Psoralens and the Skin, Paris, France
1981	Faculty, Third International Symposium on Psoriasis, Stanford University
1981	Invited Lecturer, Workshop on Biological Effects of Increased Solar Ultraviolet Radiation, National Academy of Sciences Meeting
1982	Guest Faculty, Johns Hopkins Medical Institution Course on Phototherapy
1982	Lecturer, Conference on Photobiology, Toxicologic and Pharmacologic Aspects of Psoralens, National Institutes of Environmental Health and Safety, Research Triangle, North Carolina
1983	Lecturer, Grand Rounds, University of Pennsylvania, Department of Dermatology
1984	George Fox Lecturer, New York University School of Medicine, Department of Dermatology

1984 Lecturer, Swedish Dermatologic Association, Annual Clinical Meeting, Uppsala, Sweden

1984 Lecturer, George Washington University, Drug Induced Diseases Symposium, Bethesda, MD

1985 Visiting Professor, University of Puerto Rico School of Medicine

1985 Lecturer, Second World Congress on Cancers of the Skin, New York

1985 Lecturer, Johns Hopkins School of Medicine

1985 Faculty, First International Dermatopharmacology Symposium, Vancouver, B.C., Canada

1985 Faculty, Uniformed Services University of the Health Sciences Continuing Medical Education Dermatology Conference, Mannheim, Germany

1986 Speaker, Drug Information Association Symposium: The Future of Adverse Drug Reaction Diagnosis, Arlington, VA

1986 Faculty, Second International Dermatopharmacology Symposium, Vancouver, B.C., Canada

1986 Co-chair, Phototherapy Symposium, Fourth International Symposium on Psoriasis, Stanford, CA

1986 Faculty, Anglo-Nordic Symposium on the Long Term Care of Psoriasis, Helsinki, Finland

1987 Faculty, Third International Dermatopharmacology Symposium, Vancouver, B.C.

1988 Faculty, International Symposium on Psoralens, Paris

1988 Faculty, Drug Information Association, Workshop on Cost-Benefit Analysis of Pharmaceutical Products, Hilton Head, SC

1988 Speaker, Dermatology Nurses Association, Annual Meeting, Washington, DC

1989 Speaker, National Institutes of Health Consensus Development Conference on Sunlight, Ultraviolet Radiation and Health, Bethesda, MD

1989 Lecturer, New Jersey Dermatologic Society

1989 Faculty, Fourteenth Congress of the European Academy of Allergology and Clinical Immunology, Berlin, W. Germany

1989 Speaker, Fifth Annual International Pharmacoepidemiology Conference, Minneapolis, MN

1989 Faculty, Dermatology 89: Therapeutic Update, Vancouver, B.C., Canada

1990 Lecturer, Noncognoscenti Session: Epidemiology and Clinical Research, Society of Investigative Dermatology, Annual Meeting, Washington, DC

1990 Speaker, Atlantic Dermatology Conference, Boston, MA

1991 National Institute of Arthritis and Musculoskeletal and Skin
Disease, National Research Plan Task Force Meeting, Maryland

1991 Lecturer, Eighth Advanced Course in Dermatology, Institute of
Dermatology, Brighton, England

1991 Lecturer, Skin Disease Research Center, Case-Western Reserve
University, Cleveland, OH

1991 Invited Lecturer, Annual Meeting, American Society for
Photobiology, San Antonio, TX, June 1991

1991 Faculty, Fifth International Psoriasis Symposium, San
Francisco, CA, July 1991

1991 Faculty, Institute of Dermatology's Annual Course for
Consultants and Senior Registrars, Brighton, England, February
1991

1992 Director, Forum on Epidemiology and Biostatistics, Annual
Meeting, American Academy of Dermatology, San Francisco,
CA

1992 Faculty, National Conference on Environmental Hazards to the
Skin, Washington, D.C.

1992 Lecturer, 69th Atlantic Dermatological Conference,
Washington, D.C.

1992 Faculty, International Dermatopharmacology Symposium,
Brussels, Belgium

1993 Planning Committee and Faculty, Scientific Workshop
Epidemiology of Skin Diseases, National Institute of Health,
Bethesda, MD, March 1993

1993 Lecturer, 26th Nordic Dermatologic Conference, Reykjavik,
Iceland, June 1993

1993 Faculty, American Academy of Dermatology, Washington, D.C.,
December 1993

1994 Faculty, First International Symposium on Severe Adverse
Cutaneous Reactions to Drugs, Paris, September 1994

1994 Visiting Professor, University of West Virginia School of
Medicine

1995 Lecturer, International Conference on Epidemiology of Skin
Disease, Marseille, France

1995 Invited Lecturer, American Society of Photobiology, Annual
Meeting, Washington, D.C.

1995 Faculty, American Academy of Dermatology, Annual Meeting,
New Orleans

1995 Samuel Peck Lecturer, Mt. Sinai Medical Center, NY, NY

1995 Faculty, Johns Hopkins University Postgraduate Medical
Education Course, Baltimore

1996 Lecturer, Irish Association of Dermatologists, Spring Meeting,
Cavan, Ireland

1996 Invited Lecturer, Photomedicine Society Annual Meeting,

Washington, D.C.

1996 Faculty, American Academy of Dermatology, Annual Meeting, Washington D.C.

1996 Invited Lecturer, French Dermatologic Association, Paris

1996 Faculty, Symposium on "Toxidermies", Societe Medicale des Hopitaux de Paris, Paris, France

1996 Scientific Committee and Faculty, Congress on Cutaneous Drug Reactions, Rome, Italy

1996 Invited Lecturer, Dermatology 2000, Vancouver, British Columbia

1996 Invited Speaker, Workshop on Patient Outcomes in Basal Cell and Squamous Cell Skin Cancer, National Institute of Health, Bethesda, MD

1997 Invited Speaker, Skin Disease Symposium, Israel

1998 Invited Speaker, USFDA, Dermatology Advisory Committee, Evaluation of Psoriasis, Gaithersburg, Maryland

1998 Invited Speaker, International Congress of Toxicology, Paris, France

1998 Invited Speaker, Research Workshop on Risks and Benefits of Exposure to Ultraviolet Radiation and Tanning, National Institute of Health

1998 Invited Speaker, Toxicology Forum, Given Institute, Aspen, Colorado

1999 Visiting Professor, Universities of Marseilles, Bourdeaux, and Rouen, France

2001 Speaker, Seminars in Clinical and Molecular Oncology, National Institute of Health, Bethesda, MD

2002 Visiting Professor, University of Connecticut, School of Medicine

2002 Speaker, USFDA Seminars, Drug Eruptions in Clinical Trials

2002 Invited Speaker, World Congress of Dermatology, Paris, France

2002 Invited Speaker Workshops on Burden of Skin Disease, National Institute of Health, Bethesda, MD

2003 Invited Speaker, European Academy of Dermatovenerology, Barcelona, Spain

2004 Invited Speaker, Eden Symposium How to Perform Clinical Trials for Psoriasis, University of Geneva, Geneva, Switzerland

2005 Invited Speaker, EDEN-IDEA Congress, Venice, Italy 2004

BIBLIOGRAPHY

Original Contributions

1. Wooten GF, Eldridge R, Axelrod J, Stern RS. Elevated plasma dopamine beta hydroxylase activity in autosomal dominant torsion dystonia. *N Engl J Med* 1973; 288:284-7.
2. Koch MJ, Reed D, Stern RS, Brody JA. Multiple sclerosis. A cluster in a small Northwestern United States community. *JAMA* 1974; 228:1555-7.
3. Stern RS, Eldridge R. Attitudes of patients and their relatives to Huntington's disease. *J Med Genet* 1975; 12:217-23.
4. Stern RS, Johnson ML, DeLozier J. Utilization of physician services for dermatologic complaints. The United States, 1974. *Arch Dermatol* 1977; 113:1062-6.
5. Stern RS, Jennings M, Delbanco TL, Dorsey JL, Stoeckle JD, Lawrence RS. Graduate education in primary care: an economic analysis. *N Engl J Med* 1977; 297:638-43.
6. Stern RS, Thibodeau LA, Kleinerman RA, Parrish JA, Fitzpatrick TB. Risk of cutaneous carcinoma in patients treated with oral methoxsalen photochemotherapy for psoriasis. *N Engl J Med* 1979; 300:809-13.
7. Stern RS, Morison WL, Thibodeau LA, Kleinerman RA, Parrish JA, Geer DE, Fitzpatrick TB. Antinuclear antibodies and oral methoxsalen photochemotherapy (PUVA) for psoriasis. *Arch Dermatol* 1979; 115:1320-4.
8. Stern RS, Calkins D, Lawrence R, Delbanco T. Joining a rural practice: a pilot program in primary care education in internal medicine. *J Ambul Care Manage* 1980; 1:89-95.
9. Stern RS, Zierler S, Parrish JA. Skin carcinoma in patients with psoriasis treated with topical tar and artificial ultraviolet radiation. *Lancet* 1980; 1:732-5.
10. Stern RS, Kleinerman RA, Parrish JA, Fitzpatrick TB, Bleich HL. Phototoxic reactions to photoactive drugs in patients treated with PUVA. *Arch Dermatol* 1980; 116:1269-71.

11. Stern RS, Thibodeau LA, Kleinerman RA, Parrish JA, Fitzpatrick TB, Bleich HL. Effect of oral methoxsalen photochemotherapy on cost of treatment for psoriasis. An example of technological assessment. *JAMA* 1981; 245:1913-8.
12. Melski JW, Stern RS. The separation of susceptibility to psoriasis from age at onset. *J Invest Dermatol* 1981; 77:474-7.
13. Gilchrist BA, Stern RS, Steinman TI, Brown RS, Arndt KA, Anderson WW. Clinical features of pruritus among patients undergoing maintenance hemodialysis. *Arch Dermatol* 1982; 118:154-6.
14. Stern RS, Zierler S, Parrish JA. Psoriasis and the risk of cancer. *J Invest Dermatol* 1982; 78:147-9.
15. Melski JW, Stern RS. Annual rate of psoralen and ultraviolet-A treatment of psoriasis after initial clearing. *Arch Dermatol* 1982; 118:404-8.
16. Stern RS, Melski JW. Long-term continuation of psoralen and ultraviolet-A treatment of psoriasis. *Arch Dermatol* 1982; 118:400-3.
17. Stern RS, Zierler S, Parrish JA. Methotrexate used for psoriasis and the risk of noncutaneous or cutaneous malignancy. *Cancer* 1982; 50:869-72.
18. Morison WL, Stern RS. Polymorphous light eruption: a common reaction uncommonly recognized. *Acta Derm Venereol (Stockh)* 1982; 62:237-40.
19. Paul BS, Momtaz K, Stern RS, Arndt KA, Parrish JA. Combined methotrexate--ultraviolet B therapy in the treatment of psoriasis. *J Am Acad Dermatol* 1982; 7:758-62.
20. Arndt KA, Paul BS, Stern RS, Parrish JA. Treatment of pityriasis rosea with UV radiation. *Arch Dermatol* 1983; 119:381-2.
21. Paul BS, Stern RS, Parrish JA, Arndt KA. Low intensity selective UV phototherapy. A clinical trial in outpatient therapy for psoriasis. *Arch Dermatol* 1983; 119:122-4.
22. Melski JW, Bernhard JD, Stern RS. The Koebner (isomorphic) response in psoriasis. Associations with earlier age at onset and multiple previous therapies. *Arch Dermatol* 1983; 119:655-9.
23. Read JL, Stern RS, Thibodeau LA, Geer DE, Klapholz H. Variation in antenatal testing over time and between clinic settings. *JAMA* 1983; 249:1605-9.

24. Rhodes AR, Stern RS, Melski JW. The PUVA lentigo: an analysis of predisposing factors. *J Invest Dermatol* 1983; 81:459-63.
25. Eldridge R, Iivanainen M, Stern RS, Koerber T, Wilder BJ. "Baltic" myoclonus epilepsy: hereditary disorder of childhood made worse by phenytoin. *Lancet* 1983; 2:838-42.
26. Diette KM, Gange RW, Stern RS, Arndt KA, Parrish JA. Coal tar phototoxicity: kinetics and exposure parameters. *J Invest Dermatol* 1983; 81:347-50.
27. Stern RS, Momtaz-T K. Skin typing for assessment of skin cancer risk and acute response to UV-B and oral methoxsalen photochemotherapy. *Arch Dermatol* 1984; 120:869-73.
28. Stern RS, Pass TM, Komaroff AL. Topical versus systemic agent treatment for papulopustular acne. A cost-effectiveness analysis. *Arch Dermatol* 1984; 120:1571-8.
29. Diette KM, Momtaz-T K, Stern RS, Arndt KA, Parrish JA. The role of ultraviolet A in phototherapy for psoriasis. *J Am Acad Dermatol* 1984; 11:441-7.
30. Diette KM, Momtaz-T K, Stern RS, Arndt KA, Parrish JA. Psoralens and UV-A and UV-B twice weekly for the treatment of psoriasis. *Arch Dermatol* 1984; 120:1169-73.
31. Stern RS, Rosa F, Baum C. Isotretinoin and pregnancy. *J Am Acad Dermatol* 1984; 10:851-4.
32. Stern RS, Laird N, Melski J, Parrish JA, Fitzpatrick TB, Bleich HL. Cutaneous squamous-cell carcinoma in patients treated with PUVA. *N Engl J Med* 1984; 310:1156-61.
33. Stern RS, Bigby M. An expanded profile of cutaneous reactions to nonsteroidal anti-inflammatory drugs. Reports to a specialty-based system for spontaneous reporting of adverse reactions to drugs. *JAMA* 1984; 252:1433-7.
34. Kopf AW, Kripke ML, Stern RS. Sun and malignant melanoma. *J Am Acad Dermatol* 1984; 11:674-84..
35. Stern RS, Parrish JA, Fitzpatrick TB, Bleich HL. Actinic degeneration in association with long-term use of PUVA. *J Invest Dermatol* 1985; 84:135-8.
36. Stern RS, Dodson TB. Ibuprofen in the treatment of UV-B-induced inflammation. *Arch Dermatol* 1985; 121:508-12.

37. Menkes A, Stern RS, Arndt KA. Psoriasis treatment with suberythemogenic ultraviolet B radiation and a coal tar extract. *J Am Acad Dermatol* 1985; 12:21-5.
38. Stern RS. The epidemiology of joint complaints in patients with psoriasis. *J Rheumatol* 1985; 12:315-20.
39. Stern RS, Scotto J, Fears T. Psoriasis and susceptibility to nonmelanoma skin cancer. *J Am Acad Dermatol* 1985; 12:67-73
40. Stern RS, Epstein AM. Institutional responses to prospective payment based on diagnosis-related groups. Implications for cost, quality and access. *N Engl J Med* 1985; 312:621-7.
41. Kamat BR, Tang SV, Arndt KA, Stern RS, Noe JM, Rosen S. Low-fluence CO₂ irradiation: selective epidermal damage to human skin. *J Invest Dermatol* 1985; 85:274-8.
42. Stern RS, Parrish JA, Fitzpatrick TB. Ocular findings in patients treated with PUVA. *J Invest Dermatol* 1985; 85:269-73.
43. Bigby M, Stern RS, Bigby JA. An evaluation of method reporting and use in clinical trials in dermatology. *Arch Dermatol* 1985; 121:1394-9.
44. Diette KM, Gange RW, Stern RS, Arndt KA, Parrish JA. Coal tar phototoxicity: Characteristics of the smarting reaction. *J Invest Dermatol* 1985; 84:268-71.
45. Stern RS, and the members of the 16-center PUVA Follow-up Study. Long-term use of psoralens and ultraviolet A for psoriasis: evidence for efficacy and cost savings. *J Am Acad Dermatol* 1986; 14:520-6.
46. Stern RS, Gardocki GJ. Office-based care of dermatologic disease. *J Am Acad Dermatol* 1986; 14:286-93.
47. Kamat BR, Carney JM, Arndt KA, Stern RS, Rosen S. Cutaneous tissue repair following CO₂ laser irradiation. *J Invest Dermatol* 1986; 87:268-71.
48. Stern RS, Gange RW, Parrish JA, Tang SV, Arndt KA. Contribution of topical tar oil to ultraviolet B phototherapy for psoriasis. *J Am Acad Dermatol* 1986; 14:742-7.
49. Stern RS, Armstrong RB, Anderson TF, Bickers DR, Lowe NJ, Harber L, Voorhees J, Parrish JA. Effect of continued ultraviolet B phototherapy on the duration of remission of psoriasis: a randomized study. *J Am Acad Dermatol* 1986; 15:546-52.

50. Miller KD, Lobel HO, Satriale RF, Kuritsky JN, Stern R, Campbell CC. Severe cutaneous reactions among American travelers using Pyrimethamine - Sulfadoxine (Fansidar - R) for malaria prophylaxis. *Am J Trop Med Hyg* 1986; 35:451-8.
51. Stern RS, Weinstein MC, Baker SG. Risk reduction for nonmelanoma skin cancer with childhood sunscreen use. *Arch Dermatol* 1986; 122:537-45.
52. Stern RS. Topical minoxidil. A survey of use and complications. *Arch Dermatol* 1987; 123:62-5.
53. Olbright SM, Stern RS, Tang SV, Noe JM, Arndt KA. Complications of cutaneous laser surgery. A survey. *Arch Dermatol* 1987; 123:345-9.
54. Rosen CF, Seki Y, Farinelli W, Stern RS, Fitzpatrick TB, Pathak MA, Gange RW. A comparison of the melanocyte response to narrow band UVA and UVB exposure in vivo. *J Invest Dermatol* 1987; 88:774-9.
55. Rhodes AR, Seki Y, Fitzpatrick TB, Stern RS. Melanosomal alterations in dysplastic melanocytic nevi. A quantitative, ultrastructural investigation. *Cancer* 1988; 61:358-69.
56. Bigby M, Stern RS. Adverse reactions to isotretinoin. A report from the Adverse Drug Reporting System. *J Am Acad Derm* 1988; 18:543-52.
57. Epstein AM, Stern RS, Tognetti J, Begg CB, Hartley RM, Cumella E, Ayanian JZ. The association of patients' socioeconomic characteristics with the length of hospital stay and hospital charges within diagnosis-related groups. *N Engl J Med* 1988; 318:1579-85.
58. Gupta AK, Stern RS, Swanson NA, Anderson TF. Cutaneous melanomas in patients treated with psoralens plus ultraviolet-A. A case report and the experience of the PUVA Follow-up Study. *J Am Acad Dermatol* 1988; 19:67-76.
59. Dover JS, Smoller BR, Stern RS, Rosen S, Arndt KA. Low-fluence carbon dioxide laser irradiation of lentigines. *Arch Dermatol* 1988; 124:1219-24.
60. Stern RS, Lange R. Non-melanoma skin cancer occurring in patients treated with PUVA five to ten years after first treatment. *J Invest Dermatol* 1988; 91:120-4.
61. Stern RS, Lange R. Cardiovascular disease, cancer, and cause of death in patients with psoriasis: 10 years prospective experience in a cohort of 1,380 patients. *J Invest Dermatol* 1988; 91:197-201.

62. Stern RS. Childhood sunscreen use: Factors affecting cost effectiveness. *Drug Info J* 1988; 22:471-5.
63. Stern RS. The benefits, costs, and risks of topical tar preparations in the treatment of psoriasis: considerations of cost-effectiveness. *Ann Acad Med Singapore* 1988; 17:473-6.
64. Stern RS, Khalsa JH. Cutaneous adverse reactions associated with calcium channel blockers. *Arch Intern Med* 1989; 149:829-32.
65. Stern RS. When a uniquely effective drug is teratogenic. The case of isotretinoin. *N Engl J Med* 1989; 320:1007-9.
66. Dover JS, McEvoy MT, Rosen CF, Arndt KA, Stern RS. Are topical corticosteroids useful in phototherapy for psoriasis? *J Am Acad Dermatol* 1989; 20:748-54.
67. Stern RS, Juhn PI, Gertler PJ, Epstein AM. A comparison of length of stay and costs for health maintenance organizations and fee-for-service patients. *Arch Intern Med* 1989; 149:1185-8.
68. Stern RS, Chan HL. Usefulness of case report literature in determining drugs responsible for toxic epidermal necrolysis. *J Am Acad Dermatol* 1989; 21:317-22.
69. Chan HL, Stern RS, Arndt KA, Langlois J, Jick SS, Jick H, Walker AM. The incidence of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. A population-based study with particular reference to reactions caused by drugs among outpatients. *Arch Dermatol* 1990; 126:43-7.
70. Lindelöf B, Eklund G, Liden S, Stern RS. The prevalence of malignant tumors in patients with psoriasis. *J Am Acad Dermatol* 1990; 22:1056-60.
71. Epstein AM, Stern RS, Weissman JS. Do the poor cost more? A multihospital study of patients' socioeconomic status and use of hospital resources. *N Engl J Med* 1990; 322:1122-8.
72. Stern RS and members of the Photochemotherapy Follow-up Study. Genital tumors among men with psoriasis exposed to psoralens and ultraviolet-A radiation (PUVA) and ultraviolet-B radiation. The photochemotherapy follow-up study. *N Engl J Med* 1990; 322: 1093-7.
73. Strom BL, Carson JL, Halpern AA, Schinnar R, Snyder ES, Stolley PD, Shaw M, Tilson HH, Joseph M, Dai WS, Chen D, Stern RS, Berman U, Lundin F. Using a

claims database to investigate drug induced Stevens-Johnson Syndrome. *Stat Med* 1991; 10:565-76.

74. Stern RS, Lange R, and members of the Photochemotherapy Follow-up Study. Outcomes of pregnancies among women and partners of men with a history of exposure to methoxsalen photochemotherapy (PUVA) for the treatment of psoriasis. *Arch Dermatol* 1991; 127:347-50.
75. Stern RS, Boudreaux C, Arndt KA. Diagnostic accuracy and appropriateness of care for seborrheic keratoses. A pilot study of an approach to quality assurance for cutaneous surgery. *JAMA* 1991; 265:74-7.
76. Strom BL, Carson JL, Halpern AC, Schinnar R, Snyder ES, Shaw M, Tilson HH, Joseph M, Dai WS, Chen D, Stern RS, et al. A population-based study of Stevens-Johnson syndrome: Incidence and antecedent drug exposures. *Arch Dermatol* 1991; 127:831-8.
77. Weissman JS, Stern RS, Fielding SL, Epstein AM. Delayed access to health care: risk factors, reasons, and consequences. *Ann Intern Med* 1991; 114:325-31.
78. Taylor CR, Stern RS. Magnitude and duration of UV-B induced tolerance. *Arch Dermatol* 1991; 127:673-7.
79. Stern, RS, Weissman JS, Epstein AM. The emergency department as a pathway to admission for poor and high-cost patients. *JAMA* 1991; 266:2238-43.
80. Stern RS. The prevalence of acne on the basis of physical examination. *J Am Acad Dermatol* 1992; 26:931-5.
81. Dai WS, LaBraico JM, Stern RS. Epidemiology of isotretinoin exposure during pregnancy. *J Am Acad Dermatol* 1992; 26:599-606.
82. Karagas MR, Stukel TA, Greenberg ER, Baron JA, Mott LA, Stern RS. Risk of subsequent basal cell carcinoma and squamous cell carcinoma of the skin among patients with prior skin cancer. Skin Cancer Prevention Study Group. *JAMA* 1992; 267:3305-10.
83. Caldwell-Brown D, Stern RS, Lin AN, Carter DM. Lack of efficacy of phenytoin in recessive dystrophic epidermolysis bullosa. Epidermolysis Bullosa Study Group. *N Engl J Med* 1992; 327:163-7
84. Stern RS, Albengres E, Carlson J, Chen D, Dai W, Joseph M, Tilson H, Wiholm BE, Kraft C. An international comparison of case definition of severe adverse

- cutaneous reactions to medicines. *Drug Saf* 1993; 8:67-77.
85. Bastaj-Garin S, Rzany B, Stern RS, Shear NH, Naldi L, Roujeau JC. A clinical classification of cases of toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme. *Arch Dermatol* 1993; 129:92-6.
 86. DeCoste S, Stern RS. The diagnosis and treatment of nevomelanocytic lesions of the skin: A community-based study. *Arch Dermatol* 1993; 129:57-62.
 87. Coopman SA, Johnson RA, Platt R, Stern RS. Cutaneous disease and drug reactions in HIV infection: A population based study. *N Engl J Med* 1993; 328:1670-4.
 88. Stern RS, Nelson C. The diminishing role of the dermatologist in office-based care of cutaneous diseases. *J Am Acad Dermatol* 1993; 29:773-7.
 89. Weissman JS, Stern RS, Epstein AM. The impact of patient socioeconomic status and other social factors on readmission. A prospective study in four Massachusetts hospitals. *Inquiry* 1994; 31:163-72.
 90. Stern RS, Dover JS, Levin JA, Arndt, KA. Laser therapy versus cryotherapy of lentigines: A comparative Trial. *J Am Acad Dermatol* 1994; 30:985-7.
 91. Stern RS, Laird N. The carcinogenic risk of treatments for severe psoriasis. Photochemotherapy follow-up study. *Cancer* 1994; 73:2759-64.
 92. Stern RS and members of the Photochemotherapy Follow-up Study. Ocular lens findings in patients treated with PUVA. *J Invest Dermatol* 1994; 103:534-8.
 93. Lowe NJ, Fakouhi TD, Stern RS, Bourget BS, Roniker B, Swabb EA. Photoreactions with a fluoroquinolone: evening versus morning dosing. *Clin Pharmacol Ther* 1994; 56:587-91.
 94. Stern RS. Drug promotion for an unlabeled indication: The case of topical tretinoin. *N Engl J Med* 1994; 331:1348-9.
 95. Dover JS, Geronemus R, Stern RS, O'Hare D, Arndt KA. Dye laser treatment of port-wine stains: comparison of the continuous-wave dye laser with a robotized scanning device and the pulsed dye laser. *J Am Acad Dermatol* 1995; 32:237-40.
 96. Stern RS, Fitzgerald E, Ellis CN, Lowe N, Goldfarb M, Baughman RD. The safety of etretinate in long-term use for psoriasis: Results of the etretinate follow-up study. *J Am Acad Dermatol* 1995; 33:44-52.
 97. McKenna K, Stern RS. Photosensitivity associated with combined UVB and